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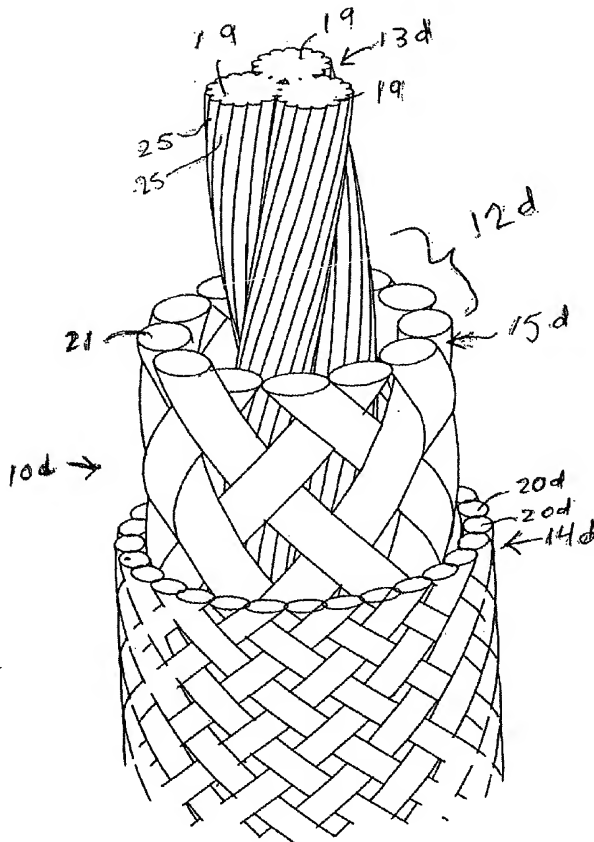
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(81) Designated States (unless otherwise indicated, for every kind of national protection available): AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BW, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NA, NI, NO, NZ, OM, PG, PH, PL, PT, RO, RU, SC, SD, SE, SG, SK, SL, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, YU, ZA, ZM, ZW.

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[Continued on next page]

(54) Title: OPTIMIZED SUTURE BRAID



(57) Abstract: A high strength abrasion-resistant surgical suture material with industry standard knot tying characteristics and color marking characteristics includes a core (12) formed of a plurality of twisted fibers (16) of a first material, surrounded by a braided cover (14) made from fibers (20) of a second material different than the first material. The first material is preferably ultrahigh molecular weight polyethylene and the second material is preferably a polymeric material having good knot-tying characteristics.

WO 2004/082724 A3

PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

REC'D 09 DEC 2004

PCT

To:
DONALD E. STOUT
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WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43bis.1)

Date of mailing
(day/month/year) 07 DEC 2004

FOR FURTHER ACTION
See paragraph 2 below

Applicant's or agent's file reference

A1916PCT

International application No.

International filing date (day/month/year)

Priority date (day/month/year)

PCT/US04/08074

18 March 2004 (18.03.2004)

18 March 2003 (18.03.2003)

International Patent Classification (IPC) or both national classification and IPC

IPC(7): A61B 17/04 and US Cl.: 606/228

Applicant

OPUS MEDICAL, INC.

1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☐ Box No. II Priority
- ☐ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☐ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI Certain documents cited
- ☐ Box No. VII Certain defects in the international application
- ☐ Box No. VIII Certain observations on the international application

2. FURTHER ACTION

If a demand for international preliminary examination is made, this opinion will be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA/ US

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**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.

PCT/US04/08074

Box No. I Basis of this opinion

1. With regard to the **language**, this opinion has been established on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.

☐ This opinion has been established on the basis of a translation from the original language into the following language _____, which is the language of a translation furnished for the purposes of international search (under Rules 12.3 and 23.1(b)).

2. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:

a. type of material

☐ a sequence listing

☐ table(s) related to the sequence listing

b. format of material

☐ in written format

☐ in computer readable form

c. time of filing/furnishing

☐ contained in international application as filed.

☐ filed together with the international application in computer readable form.

☐ furnished subsequently to this Authority for the purposes of search.

3. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.

4. Additional comments:

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/US04/08074

Box No. V Reasoned statement under Rule 43 *bis*.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)

Claims 7-11,15-22,25-33 YES

Claims 1-6,12-14,23,24 NO

Inventive step (IS)

Claims NONE YES

Claims 1-33 NO

Industrial applicability (IA)

Claims 1-33 YES

Claims NONE NO

2. Citations and explanations:

Please See Continuation Sheet

**WRITTEN OPINION OF THE
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International application No.
PCT/US04/08074

Supplemental Box

In case the space in any of the preceding boxes is not sufficient.

V. 2. Citations and Explanations:

Claims 1-6, 12-14, 23, and 24 lack novelty under PCT Article 33(2) as being anticipated by Ohi et al. (4,946,467). Ohi et al. disclose, in the figures and in col. 3, line 45 to col. 4, line 35, a suture strand with core including a plurality of core fibers made of a fibrous first material (e.g., polyester) and a cover surrounding the core, where the cover is made of a fibrous second material (e.g., silk), where the core fibers are arranged in a twisted bundle, where the cover fibers are arranged to form a woven annular band, where the first material can be deemed to have a high tensile strength material, where the core fibers comprises a bundle of filaments of the first material, where the cover fibers comprises a bundle of filaments of the second material, where each of the core fibers is substantially circular in cross section,

Claims 7-11, 20-22, and 25-29 lack an inventive step under PCT Article 33(3) as being obvious over Ohi et al. in view of Hill et al. (6,045,571). Ohi et al. disclose the invention substantially as claimed, but do not disclose a first material that comprises a high molecular, high tenacity material or polyethylene; where the second material is a polymeric material selected from the group as claimed in claim 9, where the second material is substantially opaque, where the first material is substantially transparent, and where each of the cover fibers has a substantially circular cross section and diameter greater than the diameter of each of the core fibers. Hill et al. teach, in figures 3 and 3A and in col. 7, line 17 to col. 9, line 15, a first material with a high molecular, high tenacity material or polyethylene; a second material that is a polymeric material selected from the group as claimed in claim 9, and where each of the cover fibers has a substantially circular cross section and diameter greater than the diameter of each of the core fibers. It would have been a matter of design choice to choose, a first material with a high molecular, high tenacity material or polyethylene; a second material that is a polymeric material selected from the group as claimed in claim 9, and where each of the cover fibers has a substantially circular cross section and diameter greater than the diameter of each of the core fibers. Such choices would be dependent upon the desired strength, flexibility, bioabsorbability, and hand for a suture strand. And depending on the choices of materials for the first and second materials, it would be a matter of design choice to apply a substantially opaque or transparent material. The choices would be dependent upon the type material, the thickness of material, and the desired appearance of the suture.

Claims 15 lacks an inventive step under PCT Article 33(3) as being obvious over Ohi et al. in view of Kaplan et al. (5,019,093). Ohi et al. disclose the invention substantially as claimed, but do not disclose that each of the core fibers is substantially wedge-shaped in cross section. Kaplan et al. teach, in figures 7 and 9, core fibers having a substantially wedge-shaped cross section. It would have been obvious to one having ordinary skill in the art at the time the invention was made, in view of Kaplan et al., to modify the core fibers of Ohi et al., so that they have a substantially wedge-shaped cross sections. Such a shape would produce a smooth suture strand that would allow resistance-free passage of the suture strand through tissue.

Claims 16-19 and 30-33 lack an inventive step under PCT Article 33(3) as being obvious over Ohi et al. in view of Perciacante et al. (4,047,533). Ohi et al. disclose the invention substantially as claimed, but do not disclose a core, where a sub-core comprises at least one core fiber and an outer ring comprises a plurality of core fibers. Perciacante et al. teach, in figures 1 and 2, a suture strand with a core, where a sub-core comprises a single core fiber and an outer ring comprises a plurality of core fibers. It would have been a matter of design choice to modify the suture strand of Ohi et al., so that it has the core fiber configuration taught by Perciacante et al. The choice would be dependent upon the desired strength, flexibility, bioabsorbability, appearance, and hand for a suture strand.

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.
PCT/US04/08074

Supplemental Box

In case the space in any of the preceding boxes is not sufficient.

Claims 1-33 meet the criteria set out in PCT Article 33(4), and thus a suture strand has industrial applicability because the subject matter claimed can be made or used in industry.



GB, GR, HU, IE, IT, LU, MC, NL, PL, PT, RO, SE, SI, SK, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

(88) Date of publication of the international search report:
3 February 2005

Published:

- with international search report
- before the expiration of the time limit for amending the claims and to be republished in the event of receipt of amendments

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US04/08074

A. CLASSIFICATION OF SUBJECT MATTER IPC(7) : A61B 17/04 US CL : 606/228 According to International Patent Classification (IPC) or to both national classification and IPC		
B. FIELDS SEARCHED Minimum documentation searched (classification system followed by classification symbols) U.S. : 606/228-231 Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched Electronic data base consulted during the international search (name of data base and, where practicable, search terms used) Please See Continuation Sheet		
C. DOCUMENTS CONSIDERED TO BE RELEVANT		
Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US 4,047,533 A (PERCIACCANTE et al.) 13 September 1977 (13.09.1977), See figures 1 and 2.	16-19,30-33
X	US 4,946,467 A (OHI et al.) 07 August 1990 (07.08.1990), See the figures and col. 3, line 45 to col. 4, line 35.	1-6,12-14,23,24
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Y		7-11,15-22,25-33
Y	US 5,019,093 A (KAPLAN et al.) 28 May 1991 (28.05.1991), See figures 7 and 9.	15
Y	US 6,045,571 A (HILL et al.) 04 April 2000 (04.04.2000), See figures 3 and 3A and col. 7, line 17 to col. 9, line 15.	7-11,20-22,25-29
<input type="checkbox"/> Further documents are listed in the continuation of Box C. <input type="checkbox"/> See patent family annex.		
* Special categories of cited documents:		
"A"	document defining the general state of the art which is not considered to be of particular relevance	"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"E"	earlier application or patent published on or after the international filing date	"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"L"	document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)	"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"O"	document referring to an oral disclosure, use, exhibition or other means	"&" document member of the same patent family
"P"	document published prior to the international filing date but later than the priority date claimed	
Date of the actual completion of the international search 27 July 2004 (27.07.2004)		Date of mailing of the international search report 07 DEC 2004
Name and mailing address of the ISA/US Mail Stop PCT, Attn: ISA/US Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450 Facsimile No. (703) 305-3230		Authorized officer <i>Sharon A. Greene for</i> Julian W. Woo Telephone No. 703-308-0421